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BIOLITEC, INC.

UNITED STATES DISTRICT COURT
NORTHERN DISTRICT OF CALIFORNIA
SAN FRANCISCO DIVISION

VNUS MEDICAL TECHNOLOGIES, INC.,

Plaintiff,

v.

BIOLITEC, INC., DORNIER MEDTECH
AMERICA, INC., and NEW STAR LASERS,
INC. d/b/a COOLTOUCH, INC., DAVID S.
CENTANNI, and TYRELL L. SCHIEK,

Defendant.

AND RELATED COUNTERCLAIMS.

Case No. C 08-03129 MMC

**ANSWER TO SECOND AMENDED
COMPLAINT FOR PATENT
INFRINGEMENT AND
COUNTERCLAIM OF DEFENDANT
BIOLITEC, INC.**

DEMAND FOR JURY TRIAL

ANSWER

Defendant and Counterclaimant biolitec, Inc. ("biolitec") answers the Second Amended Complaint of plaintiff VNUS Medical Technologies, Inc ("VNUS"), in accordance with the numbered paragraphs thereof, as follows:

JURISDICTION AND VENUE

1. Admitted.

2. Admitted.

1 3. biolitec admits that this Court has personal jurisdiction over it. biolitec denies the
2 remaining allegations of paragraph 3 of the Second Amended Complaint, including the allegation
3 that it has committed infringing activities.

4 4. Admitted.

5 **INTRADISTRICT ASSIGNMENT**

6 5. biolitec admits that this case is exempt from intradistrict assignment.

7 **THE PARTIES**

8 6. biolitec admits that VNUS is a Delaware Corporation with a principal place of
9 business in San Jose, California.

10 7. Admitted.

11 8. biolitec lacks sufficient information to form a belief as to the truth of the
12 allegations of paragraph 8 of the Second Amended Complaint and therefore denies same.

13 9. biolitec lacks sufficient information to form a belief as to the truth of the
14 allegations of paragraph 9 of the Second Amended Complaint and therefore denies same.

15 10. biolitec lacks sufficient information to form a belief as to the truth of the
16 allegations of paragraph 10 of the Second Amended Complaint and therefore denies same.

17 11. biolitec lacks sufficient information to form a belief as to the truth of the
18 allegations of paragraph 11 of the Second Amended Complaint and therefore denies same.

19 **THE PATENTS**

20 12. biolitec admits that copies of the patents-in-suit were attached to the Second
21 Amended Complaint as Exhibits 1-5, but lacks sufficient information to form a belief as to the
22 truth of the remaining allegations of paragraph 12 of the Second Amended Complaint and
23 therefore denies same.

24 **THE ALLEGED INFRINGEMENT**

25 13. Denied.

26 14. biolitec lacks sufficient information to form a belief as to the truth of the
27 allegations of paragraph 14 of the Second Amended Complaint and therefore denies same.

1 15. biolitec lacks sufficient information to form a belief as to the truth of the
2 allegations of paragraph 15 of the Second Amended Complaint and therefore denies same.

3 16. biolitec lacks sufficient information to form a belief as to the truth of the
4 allegations of paragraph 16 of the Second Amended Complaint and therefore denies same.

5 17. Denied.

6 18. Denied.

7 **AFFIRMATIVE DEFENSES**

8 biolitec asserts the following defenses to VNUS's Second Amended Complaint:

9 **FIRST AFFIRMATIVE DEFENSE**

10 The claims of United States Patent Nos. 6,752,803 ("the '803 patent"), 6,769,433 ("the
11 '433 patent"), 6,258,084 ("the '084 patent"), 7,396,355 ("the '355 patent") and 7,406,970 ("the
12 '970 patent") (collectively, "the Patents-in-suit") that are asserted to be infringed are invalid under
13 35 U.S.C. §§ 102 and/or 103 in view of the prior art.

14 **SECOND AFFIRMATIVE DEFENSE**

15 The claims of the Patents-in-suit that are asserted to be infringed are invalid under 35
16 U.S.C. § 112 for failure to satisfy the written description and/or enablement and/or best mode
17 requirements.

18 **THIRD AFFIRMATIVE DEFENSE**

19 biolitec has not infringed and is not infringing the Patents-in-suit and has not induced or
20 contributed to any activities of another which constitute an infringement of any of the claims of
21 the Patents-in-suit.

22 **FOURTH AFFIRMATIVE DEFENSE**

23 The Patents-in-suit are unenforceable as set forth in paragraphs 19 to 57 of the
24 Counterclaims, which are incorporated into this affirmative defense by reference.

25 **COUNTERCLAIMS**

26 biolitec counterclaims against VNUS as follows:

27 ///

28 ///

THE PARTIES

1
2 1. biolitec is a corporation organized and existing under the laws of the State of New
3 Jersey, with a principal place of business at 515 Shaker Road, East Longmeadow, Massachusetts
4 01208.

5 2. On information and belief, VNUS is a Delaware corporation and maintains its
6 principal place of business at 5799 Fontanoso Way, San Jose, California 95138.

JURISDICTION AND VENUE

7
8 3. This Court has subject matter jurisdiction over this counterclaim pursuant to 28
9 U.S.C. § 1338(a) and 28 U.S.C. § 2201.

10 4. Venue is proper in this judicial district pursuant to 28 U.S.C. §§ 1391(b), 1391(c)
11 and 1400(b).

ACTS GIVING RISE TO THE COUNTERCLAIM

12
13 5. VNUS has commenced an action against biolitec alleging infringement of the
14 Patents-in-suit.

15 6. By such action, VNUS has created an actual and justiciable case and controversy
16 between itself and biolitec concerning whether the Patents-in-suit are valid and/or enforceable, as
17 well as whether biolitec is infringing any valid and/or enforceable claim of the Patents-in-suit.

18 7. biolitec has not infringed and is not infringing any claims of the Patents-in-suit.

19 8. The allegedly infringed claims of the Patents-in-suit are invalid.

20 9. The Patents-in-suit are unenforceable.

FIRST CLAIM FOR RELIEF

(Declaratory Judgment of Noninfringement of the Patents-in-suit)

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22
23 10. biolitec repeats and realleges each and every allegation in the foregoing paragraphs
24 as though fully set forth herein.

25 11. VNUS has alleged that it is the owner of all right, title and interest to the Patents-
26 in-suit and that biolitec has infringed and is infringing one or more claims of those patents.

27 12. biolitec has not infringed and is not now infringing, either directly, contributorily,
28 or through inducement, any of the Patents-in-suit.

13. As a result of VNUS's actions and statements, including the filing of this action, an actual controversy now exists between the parties regarding the alleged infringement by biolitec of the Patents-in-suit.

14. biolitec is entitled to a declaration that it does not infringe any of the Patents-in-suit.

SECOND CLAIM FOR RELIEF

(Declaratory Judgment of Invalidity of the Patents-in-suit)

15. biolitec repeats and realleges each and every allegation in the foregoing paragraphs as though fully set forth herein.

16. biolitec is informed and believes and thereon alleges that any and all allegedly infringed claims of the Patents-in-suit are invalid for failure to satisfy the conditions for patentability set forth in 35 U.S.C. §§ 102, 103 and/or 112.

17. As a result of VNUS's actions and statements, including the filing of this action, an actual controversy now exists between the parties regarding the validity of the Patents-in-suit.

18. biolitec is entitled to a declaration that the allegedly infringed claims of the Patents-in-suit are invalid.

THIRD CLAIM FOR RELIEF

(Declaratory Judgment of Unenforceability of '803 Patent)

19. biolitec repeats and realleges each and every allegation in the foregoing paragraphs as though fully set forth herein.

20. During prosecution of the '803 patent, the claims were rejected in view of United States Patent No. 6,228,082 ("Baker patent").

21. In order to overcome this rejection, the applicants, through their attorney, asserted that "the prior art, including the references cited in the IDS submitted herewith, do not teach using tumescent technique for compressing a hollow anatomical structure."

22. This statement was incorrect, and was known to be incorrect by the applicants for the '803 patent, as evidenced by prior art articles such as Smith and Goldman, *Tumescent Anesthesia in Ambulatory Phlebectomy*, Dermatol Surg. 1998; 24:453-456, teaching that blood

vessels are compressed by the tumescent technique, and co-written by Mitchel P. Goldman, an inventor on the '803 patent.

23. These false statements were material to the patentability of the claims of the '803 patent over the Baker reference.

24. In attempting to overcome the Baker reference, the applicants, through their attorney, further argued that the tumescent technique described in Baker was directed solely to providing anesthetic and insulating effect, was limited to the "needle embodiment," and that collateral tissue damage would be less likely to occur in the catheter embodiment.

25. These statements were material to the patentability of the claims of the '803 patent over the Baker reference.

26. The Baker reference states that "The present invention may be used in combination with a tumescent technique for delivering a relatively large volume of a dilute solution of a local anesthetic agent and/or a vasoconstrictor agent to the target site." It does not limit use of the tumescent technique to any particular embodiment, nor does it exclude use of the tumescent technique for purposes known in the art other than anesthetic and insulating effect.

27. Collateral tissue damage was a continued concern even when using a catheter, and this was known by the applicants for the '803 patent, as the use of fluid to minimize unintended heating effects away from the treatment area, in conjunction with a catheter embodiment, is included in the '803 patent (col. 9, lines 10-13).

28. In making the above-noted assertions, the applicants, through their attorney, made knowing, material, misrepresentations of fact, thereby intending to deceive the Patent Office and failing to comply with the duty of candor, including the requirements of 37 C.F.R. § 1.56.

29. For reasons including the above-recited facts, the '803 patent is unenforceable due to inequitable conduct before the United States Patent and Trademark Office.

30. biolitec is entitled to a declaratory judgment that the '803 patent is unenforceable.

FOURTH CLAIM FOR RELIEF

(Declaratory Judgment of Unenforceability of '803 and '084 Patents)

31. biolitec repeats and realleges each and every allegation in the foregoing paragraphs as though fully set forth herein.

32. The '084 and '803 patents state "[t]here exists a technique referred to as tumescent anesthesia that has been used with liposuction procedures."

33. Prior to the filing date of the '084 and '803 patents, tumescent anesthesia had been taught for and used in connection with procedures other than liposuction, including phlebectomy and vein stripping procedures, which are both procedures for treating varicose veins.

34. The prior art teachings on the use of tumescent anesthesia in connection with phlebectomy and vein stripping procedures were known to the applicants of the '084 and '803 patents. Dr. Mitchel P. Goldman, one of the named inventors, authored, at least in part, material describing the use of tumescent anesthesia in phlebectomy prior to the filing dates of the '084 and '803 patents. One such reference is Smith and Goldman, *Tumescent Anesthesia in Ambulatory Phlebectomy*, Dermatol Surg. 1998; 24:453-456. In addition, Mitchel Goldman wrote a portion of a book entitled *Ambulatory Phlebectomy*, published in 1995, that taught the use of tumescent anesthesia in connection with both phlebectomy and vein stripping procedures.

35. Since the '084 patent claims methods for treating "hollow anatomical structures" and "veins", the use of tumescent anesthesia in phlebectomy and vein stripping is more relevant to the '084 patent than the use of tumescent anesthesia in liposuction. Similarly, since the '803 patent claims methods for treating "hollow anatomical structures" including veins, the use of tumescent anesthesia in vein stripping is more relevant to the '084 patent than the use of tumescent anesthesia in liposuction.

36. Prior art references disclosing the use of tumescent techniques in connection with surgical treatments for varicose veins existed prior to the filing of the '084 and '803 patent applications, including: Proebstle, et al., *High Ligation And Stripping Of The Long Saphenous Vein Using The Tumescent Technique For Local Anesthesia*, Dermatol. Surg. 1998, vol. 24:149-153; Smith, et al., *Tumescent Anesthesia in Ambulatory Phlebectomy*, Dermatol. Surg. 1998, vol. 24:453-456; and the book entitled *Ambulatory Phlebectomy*, published in 1995, with sections that

1 taught the use of tumescent anesthesia in connection with phlebectomy and vein stripping
2 procedures that were written by '084 inventor Dr. Mitchel P. Goldman.

3 37. During the prosecution of the '084 patent, no references teaching the use of
4 tumescent anesthesia in connection with phlebectomy and vein stripping procedures for treating
5 varicose veins, including those references authored in whole or in part by the inventor, Dr. Mitchel
6 P. Goldman, were disclosed to the Patent Office. During the prosecution of the '803 patent, no
7 references teaching the use of tumescent anesthesia in connection with vein stripping procedures
8 for treating varicose veins, including the reference authored by the inventor, Dr. Mitchel P.
9 Goldman, were disclosed to the Patent Office.

10 38. The withheld references relating to the use of tumescent anesthesia in connection
11 with phlebectomy and vein stripping procedures for treating varicose veins were material to the
12 patentability of the claims of the '084 patent. The withheld reference relating to the use of
13 tumescent anesthesia in connection with vein stripping procedures for treating varicose veins was
14 material to the patentability of the claims of the '803 patent.

15 39. In failing to disclose the withheld references, VNUS knowingly withheld material
16 prior art from the examiner.

17 40. In describing tumescent anesthesia as having been used with liposuction, without
18 mentioning its use in the prior art phlebectomy and/or vein stripping procedures, the applicants
19 intended to mislead the examiner, thereby further concealing material prior art.

20 41. By the above-described actions, VNUS intended to deceive the Patent Office and
21 failed to comply with the duty of candor, including the requirements of 37 C.F.R. § 1.56.

22 42. For reasons including the above-recited facts, the '084 and '803 patents are
23 unenforceable due to inequitable conduct before the United States Patent and Trademark Office.

24 43. biolitec is entitled to a declaratory judgment that the '084 and '803 patents are
25 unenforceable.

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FIFTH CLAIM FOR RELIEF

(Declaratory Judgment of Unenforceability of '084 Patent)

44. biolitec repeats and realleges each and every allegation in the foregoing paragraphs as though fully set forth herein.

45. The '084 patent is directed to "a method and apparatus for applying energy to a hollow anatomical structure such as a vein, to shrink the structure" and to using "tumescent anesthesia," i.e., dilute anesthetic solution that compresses a varicose vein prior to application of energy to the vein with a catheter.

46. On September 12, 1997, a patent application that VNUS filed pursuant to the Patent Cooperation Treaty (PCT) was published as International Publication No. WO 97/32532 (the "VNUS '532"). But for the use of tumescent anesthesia to compress the vein, the VNUS '532 describes – virtually verbatim – the same endovenous treatment method set forth in the '084 patent (e.g., inserting a catheter into the vein, positioning it at a treatment site, compressing the vein, applying energy from the end of the catheter to the compressed vein, moving the catheter while releasing energy, causing the vein to durably assume a reduced diameter, etc.).

47. As the applicant of the VNUS '532, VNUS knew of the method set forth in the VNUS '532 since at least as early as its filing date of March 4, 1997. Indeed, one of the inventors of the '084 patent, Arthur Zikorus, is also an inventor of the VNUS '532.

48. Based on the foregoing, the VNUS '532 constitutes material prior art that should have been disclosed to the Patent Office during the prosecution of the '084 patent.

49. In failing to disclose the VNUS '532, VNUS knowingly withheld material prior art from the examiner.

50. By the above-described action, VNUS intended to deceive the Patent Office and failed to comply with the duty of candor, including the requirements of 37 C.F.R. § 1.56.

51. For reasons including the above-recited facts, the '084 patent is unenforceable due to inequitable conduct before the United States Patent and Trademark Office.

52. biolitec is entitled to a declaratory judgment that the '084 patent is unenforceable.

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SIXTH CLAIM FOR RELIEF

(Declaratory Judgment of Unenforceability of '433, '355 and '970 Patents)

53. biolitec repeats and realleges each and every allegation in the foregoing paragraphs as though fully set forth herein.

54. VNUS procured at least the '084 and '803 patents through inequitable conduct.

55. The '355 patent is a continuation of the '803 patent and accordingly is unenforceable for the same reasons as the '803 patent.

56. The '433 and '970 patents are related to the '084 and '803 patents and disclose and claim subject matter that is closely related to the subject matter of the '084 and '803 patents. By asserting the '433 and '970 patents against biolitec, together with patents that VNUS procured through inequitable conduct, VNUS has come to this Court with unclean hands, thus rendering the '433 and '970 patents unenforceable.

57. biolitec is entitled to a declaratory judgment that the '433, '355 and '970 patents are unenforceable.

PRAYER FOR RELIEF

WHEREFORE, defendant and counterclaimant biolitec requests that judgment against plaintiff and counterdefendant VNUS be entered as follows:

- A. That VNUS take nothing by its Second Amended Complaint and that its Second Amended Complaint be dismissed with prejudice ;
- B. That biolitec does not infringe any of the Patents-in-suit;
- C. That the allegedly infringed claims of the Patents-in-suit are invalid;
- D. That Patents-in-suit are unenforceable as set forth in the Third, Fourth, Fifth and Sixth Claims for Relief;
- E. That the case is exceptional under 35 U.S.C. § 285 and that biolitec be awarded its attorneys' fees, costs and expenses incurred in this action as provided by that statute;
- F. Judgment in favor of biolitec against VNUS on all of biolitec's Counterclaims;

G. That biolitec have such other and further relief as the Court may deem just and proper.

DATED: September 2, 2008

COBLENTZ, PATCH, DUFFY & BASS LLP

By: _____/s/
Howard A. Slavitt
Attorneys for Defendant and Counterclaimant,
BIOLITEC, INC.

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